K023693

MAR 12 2003

510(K) SUMMARY

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**
   Airex Inc.
   13704 SE 17th Street
   Bellevue, WA 98005

2. **Contact Person:**
   William Haslebacher, President, CTO

3. **Date Prepared:**
   January 26, 2003

4. **Proprietary Name:**
   M-100 Mobile Medical Air Cleaner

5. **Common/ Usual Name:**
   HEPA Filtration system

6. **Classification Name:**
   Sec. 880.5045 Medical Recirculating Air Cleaner. A device designed to remove particles from the air for medical purposes

7. **Predicate Device:**
   The M-100 is substantially equivalent to the Micron 800M Air Purifier system by Biological Controls Inc (K974682, January23, 1998) in its design and its intended use.

8. **Device Description:**
   The M-100 is a portable HEPA-Filtered clean hood for use in providing a controlled environment to class 100 (ISO class 3.5) for medical applications that require a high degree of airborne particulate control. The system is controlled by embedded firmware and runs on standard 120volt, 5 amp power. Pushbutton Controls include airflow, light intensity, lift/lower. Manual controls include Filter tilt/angle, brakes.

   The M-100 has been designed to meet the following product safety standards:

   - UL 2601 – Standard for Medical Electrical Equipment - Part 1: General Requirements for Safety
   - ISO 14644-1 – Classification of Air Cleanliness, Cleanrooms & Associated Controlled Environments, 1999.

9. Intended Uses:

The M-100 system is intended for use in filtering airborne particles from air for medical purposes.

10. Technological Comparison to Predicate Device:

The M-100 is similar to the predicate device in that:

- Both system generate HEPA filtered air for medical purposes
- Both are portable, mobile
- Both systems are UL approved

The M-100 differs from the predicate device in that it can be used to direct highly filtered air to a specific location by means of available tilt and axial adjustments to the filter head assembly.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 2003

Mr. William Haslebacher
President
Airex Incorporated
13704 SE 17th Street
Bellevue, Washington 98005

Re: K023693
Trade/Device Name: M-100 Mobile Medical Air Cleaner
Regulation Number: 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: II
Product Code: FRF
Dated: January 28, 2003
Received: January 29, 2003

Dear Mr. Haslebacher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __K023693_____

Device Name: **M-100 Mobile Medical Air Cleaner**

Indications for Use:

The M-100 system is intended for use in filtering airborne particles from air for medical purposes.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K023693